Appl. No. 09/848,520 Atty. Docket No. 8070ML\$ Response dated April 25, 2007 Reply to Office Action of January 26, 2007 Customer No. 27752

The Applicants respectfully request that this rejection be reconsidered and withdrawn. The Applicants initially want to make the record clear that neither they, nor the applicants in Application Number 09/565,008 have ever admitted that the invention was in public use or on sale in this country, more than one year prior to the date of application for patent. The Applicants have consistently maintained that the claimed inventions were not made public.

The CAFC recently defined the state of the law relating to public use. Specifically, in *Invitrogen Corp. v Biocrest Manufacturing*, L.P., 424 F.3d 1374, 2005 U.S. App LEXIS 21516, (Fed. Cir., Oct. 5, 2005) the CAFC considered public use of a process for producing E. coli cells. In *Invitrogen*, the patentee claimed a method for producing E. coli cells. It was undisputed that the patentee kept the use of the claimed process confidential and did not sell the claimed process or products made therewith before the critical date. *Id.* at 6.

In *Invitrogen*, the CAFC held that the proper test for the public use prong of the statutory bar under 35 USC 102(b) is whether the "purported use: (1) was accessible to the public; or (2) was commercially exploited." *Id.* at 11. The CAFC further held that the test for the public use prong includes consideration of evidence relating to "the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed upon members of the public who observed the use; and commercial exploitation." *Id.* 

The *Invitrogen* court further held that secret, internal use by the patentee was not a statutory bar, because such use did not place the process, or any product derived from the process, into the public domain. *Id.* at 12. In the instant case, the process in the currently pending claims was not placed into the public domain, and no products were made using this process.

Applying the first prong of *Invitrogen* to the instant case, Applicants respectfully note these facts in *Invitrogen* are similar to the facts in the instant case. The process

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Appl. No. 09/848,520 Atty. Docket No. 8070ML\$ Response dated April 25, 2007 Reply to Office Action of January 26, 2007 Customer No. 27752

claimed in the instant application was kept confidential until after the critical date. There was neither activity that occurred in public nor public access to use of the invention. No member of the public observed the use of the claimed process, much less required confidentiality obligations therefor. Under the first prong of *Invitrogen*, the use of the claimed process by the assignee was not a public use.

The second prong of *Invitrogen*, requires commercial exploitation. Here, the *Invitrogen* court looked for more than mere "commercial benefits" to find commercial exploitation. *Id* at 12. Instead, the *Invitrogen* court, looked to see whether the invention was given or sold to another or used to create a product given or sold to another...." *Id* at 17. *Id* at 18.

Applying the second prong of *Invitrogen* to the instant case, Applicants respectfully note that neither the claimed invention nor products made therewith, were given or sold before the critical date. The claimed process is not a method of making a product. Therefore the claimed process cannot be used to create a product given or sold to another. In the instant case, products were not derived from the claimed process (as might occur when one produced the *Invitrogen* E. coli cells), sold to the public or otherwise placed into the public domain. Under the second prong of *Invitrogen*, the use of the claimed process by the assignce was not a public use.

To support a finding of public use of an invention, it is not enough that the invention simply be utilized for more than one year prior to filing. The invention must be used in a way that meets at least one of the prongs of *Invitrogen*, either 1) use accessable to the public or 2) commercial exploitation.

Both prongs of the test mandated by the CAFC in *Invitrogen*, show that no public use of the claimed invention occurred in the instant case. The rejection under 35 USC 102(b) should be withdrawn.

Appl. No. 09/848,520 Atty. Docket No. 8070ML\$ Response dated April 25, 2007 Reply to Office Action of January 26, 2007 Customer No. 27752

All of the rejections have been addressed. A new Notice of Allowance is respectfully requested.

Respectfully submitted,

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April 25, 2007 Customer No. 27752